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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/826,967 | 04/16/2004 | Tony Romeo | 14233.4USU1 | 2920 |

23552 7590 12/18/2006
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| EXAMINER |
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KETTER, JAMES S

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| ART UNIT | PAPER NUMBER |
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1636

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 12/18/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/826,967 | Applicant(s) ROMEO ET AL. | |
| | Examiner James S. Ketter | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☒ Claim(s) 1-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of embodiments employing nhaR gene in the reply filed on 28 September 2006 is acknowledged. The traversal is on the ground(s) that: 1) no search burden has been demonstrated because the classifications are the same and no reasons exist for restricting; and 2) some of the genes have very similar modes of function and operation. This is not found persuasive because: with respect to 1), see page 2, third paragraph, of the restriction requirement, wherein it was set forth that different fields of search were required. Classification in the same subclass is not material here, as sequences are not searched through the United States Patent Classification System, but through the Scientific and Technical Information Center (STIC), where a burden exists for searching more than one sequence due to heavy usage and limited capacity; and with respect to 2), the genes are not identical, and do not have identical functions, and therefore do not necessarily render one another obvious. That a biological pathway might commonly use two or more of the genes does not render one obvious over another, and does not aid in searching for sequences, as discussed above.

In view of the co-extensive nature of the search for nhaR and nhaA, the latter has been rejoined with the former and embodiments drawn to both genes are now under examination.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities:

At numerous places in the specification and drawings, there are sequences disclosed which are governed by the sequence rules. However, the embedded sequence identifiers (e.g., "SEQ ID NO:1") are absent. Applicant must provide these embedded identifiers for sequences

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disclosed in the specification, and in the Brief Description of Figures for those sequences in the figures.

Appropriate correction is required.

Claims 1-3, 5, 6, 8, 9, 11, 12 and 14-20 are objected to because of the following informalities: the instant claims contain non-elected subject matter. Appropriate correction is required.

Claims 3, 4, 6, 7, 9, 10, 12 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims recite the elected species "nhaR", but that embodiment has been omitted, presumably through typographic error, from the claims from which the instant claims depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Majernik et al. (U, newly cited).

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The instant claims are drawn to an isolated polynucleotide comprising the sequence in Figure 5 disclosing nhaR or nhaA. Claim 15 further specifies that the sequence is in a vector, and claim 16 specifies the presence of the polynucleotide in a host cell. Claim 17 specifies that the vector has a tag.

Majernik et al. teaches, e.g., at Figure 1B, a polynucleotide in a vector, cloned in an E. coli host, in vector pAM3, a clone comprising nhaR and nhaA. The IS sequences in the clone could be used as tags to identify the clone, e.g., through a hybridization protocol.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an isolated polynucleotide sequence comprising a portion of the nhaR or nhaA gene, or a sequence which is 90%, 95%, 98% or 99% homologous thereto, or which merely hybridizes to one of these under stringent conditions. This represents a large genus of potential sequences. However, the elected sequences disclosed in figure 5 are only

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partial gene sequences. To achieve a sequence that encodes a polypeptide with the disclosed function, one of skill would have needed a sufficient understanding of the relationship between the structure of a polypeptide and its function, particularly an understanding of the rules governing the folding of proteins. However, such structure-function relationships were not sufficiently understood in the prior art to know the resulting activity, i.e., function of a protein wherein the amino acid sequence had been altered. A single amino acid change can drastically alter the function or folding of a polypeptide, but the lack of reliable algorithms or complete theories in the art would not have permitted one of skill to have known if that particular change would still produce a polypeptide with the same or usably similar function to the wild type molecule. As such, one of skill in the art would not have recognized that Applicants were in possession of the full scope of the claimed invention.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
8 December 2006



JAMES KETTER
PRIMARY EXAMINER